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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,901	06/04/2001	Habib Zaghouani	ALLIA.143CP3	5455

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JOHN WURST ESQ
ALLIANCE PHARMACEUTICAL CORP
4660 LA JOLLA VILLAGE DRIVE
8TH FLOOR
SAN DIEGO, CA 92122

EXAMINER	
NOLAN, PATRICK J	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/873,901	ZAGHOUANI, HABIB	
	Examiner	Art Unit	
	Patrick J. Nolan	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-22,25-59 and 62-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22,25-59 and 62-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 19-22, 25-59, 62-68 are pending.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 19-22, 25-59 and 62-68 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/277,264. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to treating diseases with immunoglobulin fusion proteins.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has requested this rejection be held in abeyance until the resolution of the remaining issues.

The rejection is maintained.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 19-22, 25-59 and 62-65 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record set forth in the Paper mailed 7-23-04.

Applicant's arguments filed 1-24-05 have been fully considered but are not found persuasive. Applicant has argued that the structure of the claimed fusion protein is predictable (in that it is predominantly an antibody, the structure of which has been know for some time) and that T cell receptor antagonists have been identified in the prior art for many autoimmune diseases, and therefore they do not need to be disclosed in the instant specification since they would be known to skilled artisans. Applicant also has amended base claims 19 to limit the autoimmune disorder of which symptoms are being alleviated to multiple sclerosis, rheumatoid arthritis, and insulin dependent diabetes.

The examiner agrees with applicant that the generalized structure of the fusion protein is well known. However, the identity of the antagonist to be used in the fusion protein is the portion of the fusion protein that will differ in structure. The examiner agrees with applicant that T cell antagonists for multiple sclerosis, rheumatoid arthritis, and type I insulin dependent diabetes mellitus were known to skilled artisans at the time the invention was filed. However, the claims as currently recited do not require that the antigen is specific for autoreactive T cells associated with said autoimmune disorders, just that it is involved in said autoimmune disease. The structure and identity of all antigens associated with multiple sclerosis, rheumatoid arthritis, and type I insulin dependent diabetes mellitus are not found in the disclosure, and evidence indicating that said antigens were known to skilled artisans at the time the invention was filed has not been presented by Applicant. As such the rejection has been maintained.

It is noted that the instant claims recite insulin dependent diabetes, and some type II diabetic patients are insulin dependent. Type II diabetes is not considered an autoimmune disease and as such this disease has been considered by the examiner not to be part of the

disorders that can be treated using Applicant's fusion protein. If this interpretation is not correct, Applicant is invited to show evidence that antigens of insulin dependent type II diabetes were known in the art at the time the invention was filed.

Applicant argues that claims 34, 49 and 64 are actually broader than the Examiner has stated, they are not limited to treating inflammatory conditions, but are drawn to treating any disease by reducing IFN-gamma and increasing IL-10. They further argue that the written description requirement of base claims 34, 49 and 64 is met by recited functional language of the claims and that the antigens to be used are mostly known.

The Examiner respectively disagrees, all the antigens for every disease to be treated by decreasing IFN-gamma and increasing IL-10, are not known and furthermore nor are all the diseases. The Examiner used inflammation as a talking point to begin to ascertain the full scope of Applicant's claims. Applicant has described a limited number of diseases to be treated and an even further limited number of antigens to be used in Ig-constructs to treat said diseases.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 34-37, 43-52, 58-68 stand rejected under 35 U.S.C. 102(b) stand being anticipated by WO 09/09804, of record, for reasons set forth in the Paper mailed 7-23-04.

Applicant's arguments filed 1-24-05 have been fully considered but are not found persuasive.

Applicant argues that the Ig construct taught by the '804 patent would not crosslink the Fc receptors and therefore it does not meet the limitations of Applicant's claims.

However, as a first matter the Ig constructs taught by the prior art appear to have the same structure as the claimed invention, secondarily Applicant's arguments are not construed as evidenced, where evidence is required (see MPEP 2145).

7. Claim 25 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 25 lists the same antigens from the same diseases as base claim 19.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
June 6, 2005